8. SUMMARY OF SAFETY & EFFECTIVENESS

NEOMED incorporated

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	NeoMed FDA Owner/Operator #10022926 507 Hickory Ridge Trail Suite 120 Woodstock, GA 30188 Tony Lair, President Tel: 770-516-2225 Fax: 770-516-2448 Email: lair1@concentric.net
OFFICIAL CORRESPONDENT	Penny Northcutt, RAC, CQA Regulatory Consultant for NeoMed, Inc. REGSolutions, LLC Tel: 678-428-6978 Fax: 678-513-0937 Email: pennynorthcutt@theregsolutions.com
TRADE NAME:	NeoMed Single Lumen Umbilical Catheter
CLASSIFICATION NAME:	Umbilical Artery Catheter
DEVICE CLASSIFICATION	Class II per 21 CFR §880.5200
AND PRODUCT CODE	Product Code: 80 FOS
PREDICATE DEVICE NAME	CATCO Umbilical Vessel Catheter (K944368)

SUBSTANTIAL EQUIVALENCE:

The NeoMed Single Lumen Umbilical Catheter is substantially equivalent to the CATCO Umbilical Vessel Catheter cleared under K944368.

Both devices have the same method of operation to sample blood, monitor blood pressure, or administer fluids intravenously. Bench testing has demonstrated that the NeoMed Single Lumen Umbilical Catheter is functionally equivalent to predicate umbilical catheters currently on the market and that any minor differences do not affect safety or effectiveness.

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DESCRIPTION OF THE DEVICE:

The NeoMed Single Lumen Umbilical Catheter is a silicone single lumen catheter with natural white barium sulfate included for radiopacity.

The device consists of the following main components: a single lumen umbilical catheter, a hub, and a luer lock connector, and 3 way stopcock with 2 female type connectors.

INDICATIONS FOR USE:

The NeoMed Single Lumen Umbilical Catheter is intended for use in neonatal and pediatric patients to patients to sample blood, monitor blood pressure, or administer fluids intravenously.

PERFORMANCE DATA:

The NeoMed Single Lumen Umbilical Catheter materials that come in direct contact with the patient have a long history of use in umbilical catheter manufacture and are biocompatible according to ISO 10993. Functional test results demonstrate that the NeoMed Single Lumen Umbilical Catheter performs its intended use and is equivalent to the predicate device.

CONCLUSION:

Based on the performance testing, it can be concluded that the NeoMed Single Lumen Umbilical Catheter is equivalent to the predicate CATCO Umbilical Vessel Catheter with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2008

NeoMed, Incorporated
C/O Ms. Penny Northcutt
Executive Director
REGSolutions, LLC
717 Lakeglen Drive
Suwanee, Georgia 30024

Re: K073596
Trade/Device Name: NeoMed Single Lumen Umbilical Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOS
Dated: December 19, 2007
Received: December 21, 2007

Dear Ms. Northcutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K073596

Device Name: NeoMed Single Lumen Umbilical Catheter

Indications For Use:

The NeoMed Single Lumen Umbilical Catheter is intended for use in neonatal and pediatric patients to sample blood, monitor blood pressure, or administer fluids intravenously.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073596